

This listing of claims will replace all prior versions, and listings, of claims in this application.

LISTING OF THE CLAIMS:

42. (Currently Amended) A purified nucleic acid comprising:

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- (a) SEQ ID NO:3, ~~a portion thereof, or a variant thereof~~; or
 - (b) a sequence hybridizing with a complementary strand of SEQ ID NO:3 under stringent conditions, which comprise washing at 65°C in 0.1 X SSC and 0.1 %SDS;

wherein said purified nucleic acid has a transcriptional promoter activity.

43. (Currently Amended) The purified nucleic acid according to claim 42, which comprises SEQ ID NO:3 ~~or a portion thereof~~.

44. (Currently Amended) The purified nucleic acid according to claim 42, which is a *Clostridium perfringens* beta 2 toxin promoter ~~or a fragment thereof~~.

45. (Previously Added) An expression cassette comprising, in the 5' to 3' direction, the purified nucleic acid according to claim 42 and a transgene to be expressed.

46. (Previously Added) The expression cassette according to claim 45, wherein said expression cassette further comprises a transcriptional terminator at a 3' end of said transgene.

47. (Previously Added) The expression cassette according to claim 45, wherein said expression cassette further comprises a secretion signal located between said purified nucleic acid and said transgene.

48. (Previously Added) The expression cassette according to claim 45, wherein said transgene codes for a toxin, a fragment thereof, or a variant thereof.

49. (Previously Added) The expression cassette according to claim 48, wherein said toxin is a pathogenic bacterium toxin.

50. (Previously Added) A vector comprising the purified nucleic acid according to claim 42.

51. (Previously Added) The vector according to claim 50, wherein said vector is functional in a bacterium.

52. (Previously Added) The vector according to claim 51, wherein said bacterium is a *Clostridium* bacterium.

53. (Previously Added) The vector according to claim 51, wherein said bacterium is *Clostridium perfringens*.

54. (Previously Added) A recombinant cell comprising the purified nucleic acid according to claim 42.

55. (Previously Added) The recombinant cell according to claim 54, wherein said recombinant cell is a prokaryotic cell.

56. (Previously Added) A method for producing a polypeptide, comprising:

- (a) introducing a transgene coding for said polypeptide into a cell, wherein said transgene is under the control of the purified nucleic acid according to claim 42;
- (b) expressing said transgene; and
- (c) recovering said polypeptide.

57. (Previously Added) A method for producing a polypeptide, comprising:

- (a) introducing a transgene coding for said polypeptide into the recombinant cell according to claim 54, wherein said transgene is placed under the control of said purified nucleic acid;
- (b) culturing said recombinant cell to express said transgene; and
- (c) recovering said polypeptide.

58. (Previously Added) The method according to claim 56, wherein said cell is a *Clostridium* bacterium.

59. (Previously Added) The method according to claim 56, wherein said polypeptide is a toxin, a toxoid, or a fragment thereof.

60. (Currently Amended) A purified nucleic acid comprising SEQ ID NO:4 or a sequence which hybridizes under stringent conditions to a portion of SEQ ID NO:4, wherein the stringent conditions comprise washing at 65°C in 0.1 X SSC and 0.1 %SDS and, which encodes a peptide that functions as a secretion signal peptide.

61. (Previously Added) A method for producing a polypeptide, wherein said method comprises:

- (a) introducing the expression cassette according to claim 45 into a cell, wherein said transgene is placed under the control of said purified nucleic acid;
- (b) expressing said transgene; and
- (c) recovering said polypeptide.

62. (Previously Added) The vector according to claim 50, which further comprises a transgene operably linked to said purified nucleic acid.

63. (Previously Added) A recombinant cell comprising the expression cassette according to claim 45.

64. (Previously Added) A recombinant cell comprising the vector according to claim 50.


65. (Previously Added) A recombinant cell comprising the vector according to claim 62.

66. (Previously Added) The recombinant cell according to claim 54, wherein said recombinant cell is a bacterium.

67. (Previously Added) The recombinant cell according to claim 63, wherein said recombinant cell is a bacterium.

68. (Previously Added) The recombinant cell according to claim 64, wherein said recombinant cell is a bacterium.

69. (Previously Added) The recombinant cell according to claim 65, wherein said recombinant cell is a bacterium.

 70. (Previously Added) The method according to claim 57, wherein said recombinant cell is a *Clostridium* bacterium.

71. (Previously Added) A method for producing a polypeptide, comprising:

- (a) culturing the recombinant cell according to claim 63 to express said transgene in said expression cassette; and
- (b) recovering said polypeptide.

72. (Previously Added) A method for producing a polypeptide, comprising:

- (a) introducing a transgene coding for said polypeptide into the recombinant cell according to claim 64, wherein said transgene is placed under the control of said purified nucleic acid ~~on~~ said vector;
- (b) culturing said recombinant cell to express said transgene; and

- (c) recovering said polypeptide.

73. (Previously Added) A method for producing a polypeptide, wherein said method comprises:

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(a) culturing the recombinant cell according to claim 65 to express said transgene in said vector; and
(b) recovering said polypeptide.
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74. (New) A method of preparing a composition, comprising producing a polypeptide according to Claim 56, and adding the polypeptide to at least one excipient.

75. (New) A method of preparing a composition, comprising producing a polypeptide according to Claim 57, and adding the polypeptide to at least one excipient.

76. (New) A method of preparing a composition, comprising producing a polypeptide according to Claim 61, and adding the polypeptide to at least one excipient.

77. (New) A method of preparing a composition, comprising producing a polypeptide according to Claim 71, and adding the polypeptide to at least one excipient.

78. (New) A method of preparing a composition, comprising producing a polypeptide according to Claim 72, and adding the polypeptide to at least one excipient.

79. (New) A method of preparing a composition, comprising producing a polypeptide according to Claim 73, and adding the polypeptide to at least one excipient.

80. (New) The purified nucleic acid according to Claim 60, which comprises SEQ ID NO:4.

81. (New) The purified nucleic acid according to Claim 60, which comprises a sequence which hybridizes under stringent conditions to a ~~portion of~~ SEQ ID NO:4, wherein the stringent conditions comprise washing at 65°C in 0.1 X SSC and 0.1 %SDS and, which encodes a peptide that functions as a secretion signal peptide.

82. (New) A vector comprising the purified nucleic acid according to Claim 80.

83. (New) A vector comprising the purified nucleic acid according to Claim 81.

84. (New) A recombinant cell comprising the purified nucleic acid according to Claim 80.

85. (New) A recombinant cell comprising the purified nucleic acid according to Claim 81.

86. (New) An expression cassette comprising a transgene to be expressed operably linked to the purified nucleic acid according to Claim 80.

87. (New) An expression cassette comprising a transgene to be expressed operably linked to the purified nucleic acid according to Claim 81.

88. (New) A recombinant cell comprising the expression cassette according to Claim 86.

89. (New) A recombinant cell comprising the expression cassette according to Claim 87.

90. (New) A method of producing a polypeptide, comprising introducing the expression cassette of Claim 86 into a cell, culturing the cell to express the transgene; and recovering the polypeptide.

91. (New) A method of producing a polypeptide, comprising introducing the expression cassette of Claim 87 into a cell, culturing the cell to express the transgene; and recovering the polypeptide.

92. (New) A method of preparing a composition, comprising producing a polypeptide according to Claim 90, and adding the polypeptide to at least one excipient.

93. (New) A method of preparing a composition, comprising producing a polypeptide according to Claim 91, and adding the polypeptide to at least one excipient.